

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

UNITED STATES OF AMERICA,)	CASE NO. 4:19-CR-56
)	
Plaintiff,)	JUDGE BENITA Y. PEARSON
)	
v.)	
)	
THOMAS BAILEY,)	<u>DEFENDANT THOMAS BAILEY'S</u>
)	<u>MOTION TO DISMISS</u>
Defendant.)	

INTRODUCTION

Defendant, Thomas Bailey, by and through counsel, pursuant to Federal Rule of Criminal Procedure 12(b), hereby moves for an order dismissing Counts One and Nine of the Indictment against Dr. Bailey. The Indictment against Dr. Bailey is fatally flawed. The Government has improperly, and perniciously, elevated a technical DEA registration violation, under 21 U.S.C. § 842(a)(2), to the more serious charge of illegally dispensing and/or distributing controlled substances under 21 U.S.C. § 841(a)(1). The Government cannot do this. Section 842(a)(2) governs instances when a physician commits technical violations of exceeding his registration authority, which is the exact circumstance at issue in this case. There are no allegations of patient harm or lack of medical necessity in this case. On the contrary, the essential allegation against Dr. Bailey, both in Count 1 and Count 9, is simply that he illegally dispensed (or agreed to illegally dispense) Suboxone, exceeding the authority of his DEA registration, when he did not have a DATA waiver. The Government's view of the law, that simple registration violations can be charged as drug distribution violations absent more is simply incorrect. While there is no dispute that Dr. Bailey did not have a DATA waiver, this fact alone, absent allegations that Dr. Bailey

dispensed Suboxone (a) without legitimate medical purpose, and (b) outside the course of professional practice, does not amount to a § 841(a)(1) violation. Instead, such conduct only amounts to a § 842(a)(2) violation, for which Dr. Bailey is not charged. For these reasons, and those stated herein, the Indictment should be dismissed.

STATEMENT OF FACTS¹

Dr. Bailey is a physician who worked at Braking Point Recovery Center (hereinafter, “Braking Point”). Doc. 1 at ¶ 11. Braking Point hired Dr. Bailey to work in the detoxification unit of Braking Point’s Austintown, Ohio facility. *Id.* at ¶ 11. Dr. Smith, a DATA-waived physician, was the overall Medical Director of Braking Point. *Id.* at ¶ 12. Dr. Bailey was registered with federal and state authorities to prescribe Schedule II – V controlled substances; however, he did not have a DATA waiver. *Id.* at ¶ 14, 97.

The Drug Addiction Treatment Act of 2000 (hereinafter, “DATA”), permits a qualified physician to treat opioid use disorder with Schedule III – V controlled substances once that physician undergoes the required training and obtains a separate DEA registration. *Id.* at ¶¶ 13, 89.² Physicians who obtain a DATA waiver are permitted to administer, dispense, and prescribe controlled substances for maintenance and detoxification treatment. *See id.* at ¶ 91. Only those substances approved by the FDA for maintenance and detoxification treatment may be used as such. *Id.* at ¶ 89. One such approved substances is buprenorphine, a Schedule III controlled substance. *Id.* at ¶ 86. Suboxone is the name of a buprenorphine-based medication used for maintenance and detoxification treatment. *See id.*

¹ While Dr. Bailey disputes the facts contained in the Indictment, for purposes of this motion he presumes the truth of all appropriately pled factual allegations.

² This separate registration is known colloquially as a “DATA waiver.” It is known as a “waiver” because the training waives the original requirement for a physician to separately register as a Narcotic Treatment Program (“NTP”) and adhere to stringent rules and regulations surrounding such programs. *See* 21 U.S.C. § 823(g). NTP and OTP are used interchangeably within the addiction treatment community to describe the same type of facility.

The detoxification units of Braking Point, both at the Austintown and the Whitehall locations, used a protocol to help facilitate patients' detoxification treatment. *Id.* at ¶ 59, 99, 106. The protocol at the Austintown facility was titled "Opioid Withdrawal Protocol," and had a tapering schedule for Suboxone as well as specific conditional treatment options, based on a set of objective criteria, to govern the dosage. *Id.* As part of his role at Braking Point, Dr. Bailey would sign this protocol for patients in the detoxification unit. *Id.* at ¶ 60. It is the simple act—Dr. Bailey's signing of the protocol form while not having a DATA waiver—that forms the crux of the Government's case against him.³ *See e.g., id.* at ¶¶ 14, 60, 97, 101.

In February 2019, Dr. Bailey and five other individuals were charged in a multi-count indictment, with Dr. Bailey being charged in two counts: Count 1: conspiracy to commit health care fraud in violation of 18 U.S.C. § 1349; and Count 9: conspiracy to distribute controlled substances, in violation of 21 U.S.C. § 846. *See generally* Doc. 1. There are no allegations of patient harm, lack of medical necessity, or that Dr. Bailey was acting outside the scope of professional practice during his time at Braking Point. *See id.* In fact, the only substantive difference between Dr. Bailey and Dr. E.R., the *unindicted* Medical Director of Braking Point's Whitehall facility, is that Dr. Bailey did not have his DATA waiver. *See id.* at ¶ 107.

It is this simple fact, and only this fact, upon which the Government erroneously asserts that Dr. Bailey is guilty of two felony criminal conspiracies. *See generally, id.*

³ There were at least four other physicians who performed work at Braking Point and signed similar Suboxone protocol forms under similar circumstances. None of those physicians were charged. The only difference between them, as far as the defense knows, is that those physicians had DATA waivers and Dr. Bailey did not. Indeed, the protocol used at the Whitehall facility contained less individualization and was more standardized than the one used by Dr. Bailey. Thus, the case against Dr. Bailey clearly hinges exclusively on the simple fact that he allegedly dispensed Suboxone without a DATA waiver.

LAW AND ARGUMENT

I. STANDARD OF REVIEW FOR MOTION TO DISMISS

An indictment is sufficient “if it contains the elements of the offense charged, fairly informs a defendant of the charge against which he must defend and enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.” *United States v. Fitzgerald*, 366 F. Supp. 3d 903, 905 (W.D. Mich. 2017) (citing *Hamling v. United States*, 418 U.S. 87, 117 (1974)). When reviewing a motion to dismiss, the court may “make preliminary findings of fact necessary to decide questions of law...so long as the trial court’s conclusions do not invade the province of the ultimate finder of fact.” *United States v. Levin*, 973 F.2d 463, 467 (6th Cir. 1992); *see also United States v. Vertz*, 40 Fed. App’x 69, 70 (6th Cir. 2002) (stating that when a defendant argues that the undisputed facts “do not constitute the offense charged in the indictment, the Court is reviewing a question of law, not fact”). When making such determination, a court “is not limited to the fact of the indictment in ruling on the motion to dismiss since Rule 12 vest[s] the [C]ourt with the authority to determine issues of fact in such a manner as the [C]ourt deems appropriate.” *Levin*, 973 F. 2d at 467 (quoting *United States v. Jones*, 542 F.2d 661, 664 (6th Cir. 1976)).

II. THE INDICTMENT DOES NOT STATE A CONSPIRACY TO VIOLATE 21 U.S.C. § 841(a)(1) AS IT DOES NOT SUFFICIENTLY ALLEGE AN OBJECT OFFENSE TO VIOLATE 21 U.S.C. § 841(a)(1).

A. 21 U.S.C. § 841(a)(1).

The Indictment, in what it alleges and what it fails to allege, does not support a charge of conspiracy to violate § 841(a)(1). Section 841(a)(1) of the CSA states that “[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally...to [] distribute or dispense...a controlled substance.” *Id.* The United States Supreme Court has held that a physician may only be prosecuted under § 841(a)(1) if the physician’s actions “fall outside the

usual course of professional practice.” *United States v. Moore*, 423 U.S. 122, 124 (1975); *see also United States v. Johnson*, 812 F.2d 124 (6th Cir. 1987) (reiterating holding of *Moore* by stating “a physician who abuses the privilege by issuing prescriptions outside the usual course of professional practice is subject to punishment under section 841(a)(1).”). Furthermore, for a physician to be charged under § 841(a)(1), there must be facts to show that the physician dispensed the drug “without legitimate medical purpose.” *United States v. Johnson*, 71 F.3d 539, 542 (6th Cir. 1995). *see also United States v. Binder*, 26 F. Supp. 3d 565, 665 (E.D. Mich. 2014) (granting motion for judgment of acquittal and dismissing the case because the Government failed to put on evidence that the physician “prescribed the drugs without a legitimate medical purpose and outside the course of professional practice.”).

Here, the Government has not alleged that Dr. Bailey was acting outside the scope of professional practice, or that he was diverting any Suboxone from legitimate channels, or that there was a lack of medical necessity surrounding the treatment provided to the patients at Braking Point. *See Moore*, 423 U.S. at 124; *see also, Johnson*, 71 F. 3d at 542. At most, the Indictment, in Count 9, contains a single non-specific allegation that patients were admitted to Braking Point and given Suboxone “without being evaluated...to determine the medical necessity for the use of Suboxone.” Doc. 1 at ¶ 99. The Government was careful in its language, in this instance, in that it only alleged that medical necessity was not “determined,” and not that Suboxone was medically inappropriate for any patient. *Id.* This allegation alone is insufficient to assert that Dr. Bailey committed the object offense of violating § 841(a)(1), or that he was a participant in a conspiracy to violate that section. The Government alleged insufficient facts to support a conspiracy to violate § 841 because, as the Government well knows, there are none.⁴ So it has shifted to its backup plan: a

⁴ It is not surprising at all the Government steered clear of asserting that Dr. Bailey somehow dispensed Suboxone without legitimate medical purpose and outside the course of professional practice. In all of the discovery to date,

misapplication, based on its misunderstanding of, the law. Merely exceeding the scope of his registration, however, is not a violation of § 841 and cannot serve as an object of a conspiracy under the facts alleged.

Rather than focus on Dr. Bailey's conduct being allegedly outside the usual course of medical practice, the Indictment instead focuses on the simple fact that Dr. Bailey did not have a DATA waiver. *See* Doc. 1 at ¶¶ 14 (stating Dr. Bailey did not have a DATA waiver), 60 (stating Dr. Bailey "signed orders for the dispensing of Suboxone" even though he did not have a DATA waiver), 81 – 97 (providing in-depth discussion regarding DATA waiver provisions). This particular conduct, however, does not amount to a violation of § 841(a)(1) where, as here, there are no allegations that the dispensing of Suboxone was without legitimate medical purpose and outside the usual course of practice. In that instance, Dr. Bailey's conduct, as alleged in the Indictment, constitutes only a "technical violation" of the CSA – a violation which is governed by 21 U.S.C. § 842 and not § 841(a)(1).

B. 21 U.S.C. § 842(a)(2).

Section 842(a)(2) states that "[i]t shall be unlawful for *any person* who is a *registrant* to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person." *Id.* (emphasis added). A "registrant" is defined as "any person who is registered pursuant to either [21 U.S.C. 823 or 958]." 21 C.F.R. § 1300.01. When, as here, a registrant physician commits a "technical violation[,]" that physician is "liable only for the lesser penalties of sections 842 and 843" and not the more serious charge of § 841(a)(1) or conspiracy to

including the Government's own expert opinions, there is no evidence that Dr. Bailey was ever involved in providing treatment that was not medically necessary or outside the usual course of practice. To the contrary, the defense will present significant expert testimony on this point at trial—that Dr. Bailey's conduct was reasonable under the circumstances, within the standard of care and medically appropriate, and indicative of good faith. However, this factual dispute is beyond the focus of this motion—as the Government has not even properly alleged a violation of Section 841(a)(1).

commit § 841(a)(1). *United States v. Green*, 511 F.2d 1062, 1067 (7th Cir. 1975). In *Green* the Seventh Circuit listed out actions that would constitute “technical violations” of the CSA, one of which was the “dispensation of controlled substances *for which he is not authorized* to another registrant.” *Id.* at 1067. (emphasis added). The court in *Green* went on to further state that it is only when “a physician acts without any legitimate medical purpose and beyond the course of professional practice...[that] his conduct should be treated like that of any street-corner pill-pusher.” *Id.* Implicit in this statement is the realization that a physician registrant who dispenses controlled substances for which he is not registered may not be “treated like that of any street-corner pill-pusher,” unless he acts “without legitimate medical purpose and beyond the course of professional practice.” *Id.* There is no such allegation against Dr. Bailey.

In *United States v. Blanton*, the Eleventh Circuit held that, a registrant may be held criminally liable under § 841, if, unlike in this case, he dispenses a controlled substance for which he is ***not registered at all***, even if he acts within the usual course of professional practice. 730 F.2d 1425, 1430 (11th Cir. 1984). While the Government may argue that *Blanton*, is directly on point and forecloses this argument, the case is distinguishable and not persuasive.

In *Blanton*, the defendant willfully dispensed methaqualone, for which he was not registered to dispense under *any* circumstances. 730 F.2d at 1430. Here, however, Dr. Bailey was registered to dispense Schedule III drugs, which includes buprenorphine-based products, like Suboxone. In other words, Dr. Bailey, unlike the physician in *Blanton*, *was* registered to dispense buprenorphine to *any* patient for purposes of, for instance, pain management. Dr. Bailey is only accused of exceeding his registration because he did not have the DATA waiver to dispense within the confines of Braking Point’s detoxification program. Furthermore, unlike here, the defendant in *Blanton* was also put on notice that his registration did not cover methaqualone, and yet he

willfully dispensed methaqualone anyway. *Id.* at 1428. Dr. Bailey was unaware that the mere signing of a protocol constituted dispensing Suboxone, and he is not alleged to have willfully violated Section 841(a)(1). Indeed, the defense is not aware of a single case holding that the mere dispensing of Suboxone without a DATA waiver amounts to a § 841(a)(1) violation.

Despite the claims the Government may make, *Blanton* actually supports Dr. Bailey's position that § 841 should not apply in this case because he was in fact registered for buprenorphine, unlike the physician in *Blanton*. In *Blanton*, the court instructed the jury that it could find the defendant guilty if "the defendant was not registered to possess, distribute, or dispense methaqualone" or if he was in fact registered, if he "possessed, distributed or dispensed other than in the course of professional practice and other than for a legitimate medical purpose," or if the defendant "knowingly and willfully" dispensed or distributed methaqualone. *See* 730 F.2d at 1429 fn. 2. This instruction supports Dr. Bailey's, not the Government's, position. As stated, Dr. Bailey, unlike the physician in *Blanton*, was indeed registered for buprenorphine-based products under his Schedule III registration. The Government does not allege, and certainly will be unable to prove, that Dr. Bailey's actions were outside "the course of professional practice and other than for a legitimate medical purpose." *Id.* Finally, the Government does not allege Dr. Bailey knowingly or willfully distributed or dispensed buprenorphine. Thus, his conduct, as alleged in this case, does not fall within the purview of § 841(a)(1), despite the Government's contentions to the contrary.

1. **Section 842 governs in this case because Dr. Bailey's conduct only amounts to a technical violation of his registration.**

Dr. Bailey is a "registrant" under the federal regulations because he is registered to prescribe and dispense Schedule II – V controlled substances. *See* 21 U.S.C. § 823(b); (e) (describing the registration requirements for an applicant to distribute Schedule II – V controlled

substances).⁵ Because Dr. Bailey is registered for Schedule III substances, he is authorized to dispense buprenorphine. A DATA waiver permits a registrant to extend his registration to include dispensing buprenorphine for detoxification purposes. If a registrant does not have a DATA waiver, and still dispenses buprenorphine for detoxification purposes, the registrant would be exceeding the scope of his registration. This is the exact type of conduct that Dr. Bailey is charged with committing. The crux of the Government's allegations against Dr. Bailey are that he allegedly dispensed Suboxone without having a DATA waiver. *See* Doc. 1 at ¶¶ 14, 60, 97. And this is the exact type of conduct that § 842, not § 841(a)(1), was designed to exclusively cover.

The Government, however, has inappropriately elevated Dr. Bailey's conduct, conduct which is only a "technical violation," to the more severe violation of § 841(a)(1), without alleging or providing any evidence that Dr. Bailey's conduct was without legitimate medical purpose or outside the usual course of professional practice. This is contrary to law. The CSA, as interpreted by the United States Supreme Court and the Sixth Circuit, require that in order for the Government to subject a physician registrant to its serious felony penalties the Government must allege and prove that the physician's conduct was "outside the usual course of professional practice," and that he was acting "without legitimate medical purpose." *Moore*, 423 U.S. at 124; *Johnson*, 71 F.3d at 542.

If the Government's issue is that Dr. Bailey was providing improper or insufficient medical care because he was using a protocol, then it would follow that any physicians who used a protocol, including those based at the Whitehall facility, should also have been included in the

⁵ While these sections use the term "distribute," these are the applicable registration requirements for a physician to dispense and/or prescribe Schedule II-V controlled substances. *See Maynard v. Drug Enforcement Admin.*, 117 F. App'x 941, 943 (5th Cir. 2004) (citing *Trawick v. Drug Enforcement Admin.*, 861 F.2d 72, 75 (4th Cir. 1988) (stating that the "CSA requires that every practitioner who *dispenses* or distributes any controlled substance in connection with his practice obtain a certificate of registration.")).

Indictment; but, those physicians were not indicted alongside Dr. Bailey. Indeed, the only difference between Dr. Bailey and the unindicted physician from Whitehall is that he had a DATA waiver while Dr. Bailey did not. *Id.* at ¶ 107 (stating that Dr. E.R. was a “DEA DATA waived physician”).

Thus, it is clear the Government is fixated on the fact that Dr. Bailey did not have a DATA waiver, a fact which has been made clear from the Indictment, the Government’s charging decisions, and representations made by the Government throughout this case. *See e.g.*, Doc. 1 at ¶¶ 14, 60, 97, 106. The main issue is not about patient care as the Government would like to argue; but rather, it is about a mere technical violation by Dr. Bailey. It is improper to take this mere technical violation and use it to impute responsibility onto Dr. Bailey for health care fraud and improperly dispensing controlled substances. This overzealous action and improper charging decision by the Government has already resulted in Dr. Bailey’s Medicaid privileges being suspended and thus, his privileges at the hospital also being suspended as a result. Further, under the Government’s contention, Dr. Bailey’s misunderstanding of a complex regulatory scheme, which resulted in him unwittingly exceeding his registration, is enough to subject him to a drug felony; despite the existence of § 842(a)(2), which was designed for this exact type of case.

Taking the Government’s allegations in the Indictment against Dr. Bailey as true would not amount to a § 841(a)(1) violation; but rather, it would amount to, if anything, a § 842(a)(2) violation given that Dr. Bailey is a registrant and the impetus of the case against him is based on a technical violation. For these reasons alone, the Indictment should be dismissed.

2. **Allowing this case to proceed under conspiracy to violate § 841(a)(1) would render § 842(a)(2) obsolete.**

It is a well-known rule of statutory construction that a court “must give effect, if possible to every clause and word of a statute.” *United States v. Medlock*, 792 F.3d 700, 709 (6th Cir.

2015). Section 841(a)(1) was designed to curtail the diversion of controlled substances “from legitimate channels to illegitimate channels,” which is not at issue in this case. *Moore*, 423 U.S. at 135 (citing H.R. Rep. No. 91-1444 at p. 6; S.Rep. No. 91-613, p. 4). Section 842, on the other hand, was designed to provide a more appropriate penalty structure for registrants who may violate the terms of their registration, but whose conduct amounts to nothing more than a technical violation. *See Green*, 511 F.2d at 1067.

Allowing the Government to pursue a claim against Dr. Bailey based purely on the issue of him not having a DATA waiver renders § 842 redundant to the statutory provisions in § 841. If § 841(a)(1) governed all conduct by a physician that exceeded the scope of his registration there would be no need for Congress to enact § 842(a)(2), which contains language to specifically deal with instances where a registrant distributes or dispenses a controlled substance, “not authorized by his registration.” § 842(a)(2). The Government’s interpretation of the statutory framework ignores the “not authorized by his registration” clause in § 842(a)(2) and renders that statutory provision obsolete, all in violation of well-known statutory construction rules. *See Medlock*, 792 F.3d at 709. Indeed, even if § 841(a)(1) was meant to encompass willful dispensing violations in contravention of a registration (which it was not), there would have been no need for Congress to explicitly include statutory language stating that a “knowing” violation of § 842 shall amount to a misdemeanor. *See* § 842(c)(2)(A). Congress carefully crafted the complex statutory language in the CSA. The Government cannot usurp Congress’s authority by willfully ignoring that well-balanced language simply because it is looking for a greater criminal penalty.

Furthermore, to the extent reading § 841(a)(1) and § 842(a)(2) in conjunction with one another creates a conflict between the statutes, the Government should not get to choose which interpretation best suits its needs; rather, the rule of lenity should apply in favor of Dr. Bailey’s

interpretation. The rule of lenity requires that courts “when faced with two equally-persuasive interpretations of a criminal statute, accept the defendant’s construction.” *United States v. Rockymore*, 909 F.3d 167, 172 (6th Cir. 2018). Given that there are two possible interpretations of the statutory framework involved in this case, the rule of lenity applies, and Dr. Bailey’s interpretation governs. Under Dr. Bailey’s interpretation, which is the most logical interpretation, his conduct, as alleged in the Indictment, is covered by § 842, which has not been charged, and not § 841, which has been charged as the object of the alleged conspiracy. Thus, per the intent of Congress, Dr. Bailey should only be subject to the penalties set forth in § 842. For these additional reasons, the Indictment should be dismissed.

CONCLUSION

In this case, the Government is attempting to create a felony where one does not exist. To allow this case to go forward, under these circumstances, would permit the Government to criminalize physicians who, despite their best efforts, were not able to adequately navigate a highly technical and complex regulatory environment. The legislative branch unequivocally determined that technical violations of a physician’s registration, such as the violations alleged in this case, would be governed by § 842 and punishable by, at worst, a misdemeanor. Prosecutorial discretion does not permit the Government to circumvent the intention of Congress by inflating mere technical violations into felonious criminal conspiracies. And neither should this Court.

For these reasons, and the reasons stated herein, Dr. Bailey requests that his motion be granted, and Count One and Count Nine dismissed against him.

Respectfully submitted,

/s/ Paul M. Flannery

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CERTIFICATE OF SERVICE

I hereby certify that on September 17, 2019, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Paul M. Flannery
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Attorney for Defendant Dr. Thomas Bailey